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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,024	09/25/2006	Werner Mederski	MERCK-3237	7329
23599 7590 04/24/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER SHAMEEM, GOLAM M				
ART UNIT		PAPER NUMBER		
1626				
NOTIFICATION DATE		DELIVERY MODE		
04/24/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

### Office Action Summary

**Application No.**

10/594,024

**Applicant(s)**

MEDERSKI ET AL.

**Examiner**

Golam M. M. Shameem

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/US)
- Paper No(s)/Mail Date 09/25/2008
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

This application is a 371 of PCT/EP05/02306 03/04/2005, is acknowledged.

### ***Status of Claims***

Claims 1-16 are currently pending in the application.

Receipt is acknowledged of amendment / response filed on April 09, 2009 and that has been entered.

Claims 10-16 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

### ***Information Disclosure Statement***

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 09/25/2006, which has been entered in the file.

### ***Response to Election/Restriction***

In response to the restriction requirement, Applicants have elected Group I, which includes claims 1-8, drawn to a compound of the formula I and the elected species as set forth found in Example 1 on page 29, with traverse is acknowledged. Applicant's arguments (to withdraw the restriction requirements) have been fully considered and found partially persuasive and therefore, Examiner has agreed to modify the restriction requirements to include and examine Group II, claim 9 together with the elected invention of Group I, because it commensurates within the scope of the elected invention.

However, the Examiner respectfully disagrees with the Applicant's other arguments at this time because the Invention groups I-VI differ materially in structure and in element from

each other and therefore, are capable of supporting their own patents. The invention Groups I-VI each relate to a set of structurally diverse and dissimilar compounds [having different variable groups, which are attached directly and indirectly to the formula I], process for preparing, and their methods of use, which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious. The core does not define a contribution over the art. The ring structure of formula I is further substituted by different variables such as R, R<sup>1</sup>, R<sup>2</sup>, and R<sup>4</sup> etc, which are broadly defined and when the compound of formula I is taken as a whole, a plethora of vastly different compounds are possible. Thus, these features are not considered 'special technical features' under PCT rules 13.1 and 13.2. Hence, the unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

In addition, 35 U.S.C. 372 (b)(2) clearly states that unity of invention may be reexamined under 35 U.S.C. 121. Restriction was based on PCT Rule 13.1, 13.2 and Annex B part 1(b) together with 37 CFR 1.475 and 1.499 for lacking unity of invention because of lacking a significant structural element qualifying as the special technical features.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B (2)(V) when dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the Examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised. If the Examiner finds one of the inventions unpatentable over the prior art the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention. Nevertheless, Examiner may reconsider to rejoin one method of use claim commensurate in scope with the product claims when the case would be found in condition for allowance [provided those method of use claims are free from 35 U.S.C. §112 first (including written description, reach-through claim language and/or scope-enablement issues) and second paragraphs]. For these reasons, Applicant's arguments are found unpersuasive and, since 35 U.S.C. 101 allows one patent per invention, the requirement for restriction (election of species) is still deemed sound and proper.

Applicants preserve their right to file a divisional on the non-elected subject matter.

As set forth in the restriction requirement and an election of a single compound (or set of compounds), the scope of the invention which has been examined, inclusive of the elected species is as follows:

A compound of the formula I as shown in claim 1 wherein:

R is Hal,

R<sup>1</sup> is as claimed except "OA",

R<sup>2</sup> is as claimed,

R<sup>3</sup> is as claimed,

R<sup>4</sup> denotes  $-C_6H_4-(CH_2)_n-NR^5R^{5'}$ ,

and all other variables are as claimed.

As a result of the election and the corresponding scope of the compound identified, claims 10-16 and the remaining subject matter of claims 1-9 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn subject matter of claims 10-16 is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct therefrom.

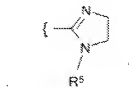
***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-8 are rejected under 35 U.S.C. § 102(e) as being anticipated by Bigge *et al* (2003). Applicant claims a compound of formula I [Prolinyl derivatives], compositions and the methods of use thereof. Bigge *et al* also disclose the synthesis of several substituted pyrrolidine dicarboxamides compounds and at least one of them anticipates the instantly claimed invention wherein R is Hal (Cl), R<sup>1</sup> is OA [wherein A is alkyl, such as, (Me)], R<sup>2</sup> is H, R<sup>3</sup> is Hal (F) and R<sup>4</sup>



[wherein R<sup>5</sup> is alkyl, such as, (Me)], [STN International, HCAPLUS

database, RN number, 536750-92-2, a copy is provided with this Office action], which reads on the instantly claimed compound.

### ***Objections***

Claims 1-9 are objected to for containing non-elected subject matter. The claims should be amended to exclude non-elected subject matter and within the scope of elected compound.

The expression “solvates” should be deleted from claim 1 (page 3, line 2, and all other occurrences of claims 2-9) because the term is undefined by Applicant’s disclosure.

Claim 9 is objected to as being dependent upon a rejected base claim 1 but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone number for this Group is (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) “Official” for papers that are to be entered into the file, and “Unofficial” for draft

documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

/Golam M. M. Shameem/  
Primary Examiner  
Art Unit 1626  
Technology Center 1600



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